Stratton VA Medical Center Institutional Review Board Standard Operating Procedure: Suspension & Termination of Approved Research

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state, and local regulations in the conduct of human subject research studies. Written procedures are required to suspend or terminate approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious risk or harm to subjects. Written procedures are required for reporting the suspension or termination to the investigator, appropriate institutional officials, and applicable federal agencies and sponsors.

REFERENCE DOCUMENTS

45 CFR 46

21 CFR 50, 56

38 CFR 16

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

PROCEDURE

Authority to suspend or terminate research or participation of researchers as defined below:

Suspension of Research: A directive of the IRB or the IRB Chair or designee to temporarily or permanently stop some or all research procedures or activities pending future action by the IRB or by the Investigator or his/her study personnel.

Termination of research: A directive of the IRB to permanently stop all or some research procedures.

The IRB Chair (or designee) or Institutional Official (IO) may suspend:

- A research principal investigator's (PI) research activities and/or one or more of the studies overseen by a PI, and/or
- A research investigator's research activities and possibly one or more of the studies which that investigator is involved in, depending on the severity of the deviations from compliance.

Suspension will be immediate if:

- There is reasonable concern that subjects are at increased risk and there is inadequate time for convening an IRB meeting to determine if a suspension should take place or

- If research participants' personal health information has been or is believed to have been compromised.

- Other non-compliance determined to be serious and necessitating immediate action

Suspension will occur after full IRB review if:

- The research is not being conducted in accordance with IRB requirements, or

- The research is associated with unexpected serious risk or harm to subjects, or

- The IRB finds reasonable cause to remove the PI from the study.

If the IRB Chair or designee suspends or terminates any approved research or investigator's research activity:

- After immediate suspension, the IRB Chair, or designee will expeditiously (within 10 days) report the action to the R&D Chair, Research and Development Committee, IO, PI and others as appropriate (e.g. FDA, OHRP, etc.).
- The research will be placed on the agenda of the next scheduled IRB meeting.
- The IRB will approve, modify, or reverse the suspension or termination
- The IO may approve or reject the IRB decision, but may not reverse the decision to suspend made by the IRB.

Communication of Suspension to Investigator

Upon determination of full-board suspension, or immediate suspension, by the appropriate parties (see above), the investigator will receive immediate notification. Communication will be in the form of a letter. Communication may also be in the form of email or phone call in order to expedite notice, though a formal letter will be drafted and delivered by with 5 days.

The IRB Chair or designate, and/or the IO or designate, will draft and deliver the notice of suspension.

The notification of suspension to the investigator will include a clear description of the steps required for remediation to lift the suspension. If further steps for remediation are determined by the IRB or IO at a later time (e.g. next scheduled IRB meeting), then those steps will be communicated to the investigator.
The notification will clearly indicate any restrictions resulting from suspension. Such restrictions may include removal of access rights to research areas, removal of access to VA computer systems, return of data or equipment to Stratton VAMC R&D program office, or restrictions as determined by the IRB and/or IO.

The investigator will inform the IRB when the remediation requirements are complete. The investigator will then receive a letter confirming the completion of steps required for the lifting of suspension.

Subject protection after suspension or termination

If approved research, or a research staff person's participation in research, is suspended or terminated, the IRB will consider alternatives that protect subjects currently enrolled in the research.

When required for subject safety, the IRB Chair or designee will directly notify PI(s) of suspension or termination of approved research. If the PI is unavailable, the IRB Chair or designee will directly notify the IO(s) about the suspension or termination of approved research.

Once notified of the suspension, the investigator must immediately cease all research activities including recruitment, enrollment, interventions, interactions and the collection of private identifiable data and submit to the IRB Chair or designee a list of research subjects for whom suspension of the research would potentially cause harm. The IRB Chair or designee, in consultation with the Chief of Staff (COS), will determine if the subjects may continue in the research or be withdrawn by reason of ensuring participant safety and/or protecting participants' rights.

In the absence of the PI, the IRB Chair or designee, in consultation with the COS, will determine an appropriate qualified interim individual to assume the responsibilities of the study.

If the PI does not respond to the IRB request by the deadline indicated, the IRB Chair or designee will contact IO(s) to determine if the participants may continue in the research or, in the interest of safety, be withdrawn.

In consideration of safety, the IRB Chair, or designee or full committee must consider the implications the suspension or

termination of a study or researcher might have for the participants; therefore a determination of whether the participants enrolled in the study need to be informed of its suspension or termination. Generally, this would be based on the nature of the study and the degree of involvement of the participants. Informing the participants may be of benefit to both the participants and the study by providing additional safety and a sense of security to the participants, while facilitating the tracking of undesirable consequences or events that led to the suspension or termination of the study.

The IRB Chair, designee or IO who orders the suspension or termination will require that an investigator or designee continue to report all adverse events (AE) and outcomes in suspended or terminated studies, to the IRB.

Reporting of suspension or termination of protocol or research staff activities

The IRB staff will send to the PI a written notification of suspended or terminated research within 5 business days of the decision.

The reasons for the suspension or termination will be included in the notification.

A copy of the notification will be sent to the:

- IRB
- Office of Research and Development for VA funded Research and Office of Research Oversight
- Chair, R&D Committee
- Appropriate institutional officials, including the Medical Center Director, the Chief of Staff, and the Research Compliance Officer
- VA Privacy Officer when the report involves unauthorized use, loss or disclosure of identifiable patient information
- VHA Information Security Officer, when report involved violations of VA information security requirements.

If the DHHS regulates the research, the IRB Chair or designee will forward a copy of the notification to OHRP within 10 business days of the decision.

If the FDA regulates the research, the IRB Chair or designee will forward a copy of the notification to the FDA within 10 business days of the decision.

The IRB Chair or designee will forward a copy of the notification to Office of Research Oversight (ORO), OHRP and the Research Compliance Officer within 10 business days of the decision.

If a federal agency other than FDA or OHRP funded the research, the IRB Chair or designee will forward a copy of the notification to the applicable federal agency within 10 business days of the decision.

If a sponsor other than a federal agency funded the research, the IRB Chair or designee will forward a copy of the notification to the sponsor within 10 business days of the decision.

Any reports directed to agencies or sponsors outside the VA will be approved and signed by the facility's Director.

Removal of suspension

The investigator will submit a written response to the IRB within 15 days of the date of the suspension letter. In the response, the investigator must provide justification for the removal of the suspension.

The letter of justification will be reviewed at the next scheduled IRB meeting. The IRB will make a determination of whether or not to lift the suspension or terminate the study.

IRB review and re-approval must occur prior to re-initiation of the research.

Suspended protocols will remain on the continuing review schedule associated with the most recent successful IRB initial or continuing review approval. At the next continuing review, the suspended protocol will be reviewed and may be 'tabled,' suspension extended, or closed, based on the recommendations of the IRB after thorough review of conditions of the suspension.

Records

The date the approved research is suspended or terminated by the IRB is recorded in the active research protocol database.

The file is removed from the active files to be processed for termination by R&D. The file is then labeled as terminated and stored for at least five years after termination.

Suspended studies or individual investigators suspended from research activities will remain as business items on each monthly IRB agenda until a final determination on the status of the suspension is made.